

Message Text

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PAGE 01 STATE 096631
ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-12 ISO-00 OES-07 MMO-04 EB-08
SIG-03 COME-00 CIAE-00 INR-10 NSAE-00 PA-02 /065 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VB
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: REVANS
EA/ANP:TWAJDA
EUR/NE:SWORREL
EUR/WE:BMCKINLEY
EUR/NE:WNEWLIN
EUR/WE:AHUGHES
EUR/WE:JDOBBINS
EUR/CE:JHURLEY,JR
EA/ANP:WGALLAGHER
EUR/CE:ELAUDERDALE

-----028441 150532Z /20

P 142158Z APR 78
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY
AMEMBASSY LONDON PRIORITY
AMCONSUL MILAN PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY THE HAGUE PRIORITY
AMEMBASSY VIENNA PRIORITY
AMEMBASSY PARIS PRIORITY
AMCONSUL HONG KONG PRIORITY
AMEMBASSY WELLINGTON PRIORITY
AMEMBASSY BONN PRIORITY
AMCONSUL BILBAO PRIORITY
INFO AMEMBASSY ROME PRIORITY
AMCONSUL BARCELONA PRIORITY

UNCLAS STATE 096631

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 096631

E.O. 11652: N/A

TAGS:OGEN, ETRD, EIND, TBIO, AS, UK, IT, BE, SP, NL, AU,

SUBJECT: FDA ADVISORY - REVISED PRODUCT LABELING
(RECALL T-004-8)

1. FDA ADVISES OF THE FOLLOWING:

PRODUCT INVOLVED: SUBCLAVIAN JUGULAR CATHETER SET CATALOGUE NO. 755. A PRE-STERILIZED SET CONSISTING OF NEEDLE/SYRINGE ASSEMBLY, PLASTIC CATHETER, LUER TWIST ADAPTER, AND CATHETER SUPPORT. THE SET IS INTENDED TO BE USED TO: MONITOR CENTRAL VENOUS PRESSURE, FOR INTRAVENOUS HYPERALIMENTATION AND OTHER IV PURPOSES. INDIVIDUALLY WRAPPED UNITS ARE PACKED IN CARDBOARD CARTONS FOR SHIPPING. 25 UNITS/CAN.

2. PRODUCT IDENTIFICATION: THE SETS ARE DESIGNED AS SUBCLAVIAN JUGULAR CATHETER SET NO. 755. ALL SETS ARE SOLD UNDER THE DESERET LABEL. LOT NUMBERS INVOLVED ARE X1-798-045 THROUGH X1-633-087, X IS PRODUCT MANUFACTURER, AFTER 1973 RECALL; 1 IS STERILIZER USED: 798/633 IS WORK ORDER NUMBER ASSIGNED CONSECUTIVELY THROUGH 999 AND THEN REPEATED: 045/087 WORK ORDER DATED APRIL 1975 THROUGH AUGUST 1977.

3. RECALLING FIRM: DESERET PHARMACEUTICAL CO, INC.,
450 SOUTH STATE, SANDY, UTAH 84070

4. REASON FOR RECALL: A TOTAL OF 17 COMPLAINTS REPORTED TO FDA OR FOUND IN THE FIRM'S COMPLAINT FILES INVOLVED THE DISCONNECTION OF CATHETER TUBING FROM THE ADAPTER COUPLING. ALTHOUGH NOT THE CAUSE OF DEATH TWO CATHETER UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 096631

NEEDLES WERE FOUND LODGED IN A PATIENT'S CORONARY AND FEMORAL ARTERY DURING AUTOPSY. BREAKING AND SPLITTING OF THE CATHETER IN-USE WERE REPORTED BY HOSPITALS, AS WELL AS INSTANCES OF CATHETER/ADAPTER IN-USE DISCONNECTION. NO INJURIES ARE YET ATTRIBUTED TO THE DEVICE. THESE DEFECTS CAN RESULT IN EMBOLISMS, ENVIRONMENTAL CONTAMINATION OF THE CATHETER TUBE, AND/OR SEPSIS. EXPLANATION OF DEFECTIVE UNITS ALSO PRESENTS A SURGICAL RISK.

5. THE FIRM HAS MODIFIED THE "SCREW-ON" ADAPTER AT LEAST TWICE SINCE 1975, YET CLAIMS THAT ALL COMPLAINTS/MALFUNCTIONS ARE DUE TO POOR PHYSICIAN TECHNIQUES. ON 9/6/77 THE FIRM ISSUED A MEMO TO ITS SALESMEN INSTRUCTING THEM TO PLACE REVISED LABELING IN A PROMINENT HOSPITAL LOCATION.

6. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED REVISED LABELING FROM FIRM AND EXPLANATORY LETTERS AND MEMORANDA DATED SEPTEMBER AND OCTOBER 1977. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING "RECALL" SHOULD BE DIRECTED TO FIRM. NOTE- PRODUCT IS NOT BEING WITHDRAWN FROM MARKETING BUT MERELY

REQUIRES RELABELING.

7. FOREIGN CONSIGNEES AS FOLLOWS:

WILLIAM PEARCE AND CO., PTY LTD.
P.O. BOX N69
SYDNEY HALL EXCHANGE 2012
AUSTRALIA

MR. WILLIAM R. MACKENZIE, DIRECTOR
MC CARTHYS SURGICAL LTD.
SELINOS LANE
DOGENHAM RM8 100
ESSEX, ENGLAND
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PAGE 04 STATE 096631

MR. RON SHILLING, DIRECTOR
DANIELI S.P.A.
VIA CARLO REVIZZO 36/1
20149 MILANO, ITALY

AMS/BELGIUM (PAUL LOUIS) PERTH SURGICAL SUPPLY CO.
CHOUSSEE DE ZELLIK 30 PTY LTD.
1080 BRUSSELS, BELGIUM 31 SUNDERCOMBE ST.
-- P.O. BOX 18
WARNER AND WEBSTER PRY. LED. OSBORNE PARK 6017
273 INKERMANN ST. WEST AUSTRALIA
ST. MILDO 3182
P.O. BOX 84
VICTORIA, AUSTRALIA

ESTABLECIEMIENTOS SUMISAN
MIROCRUZ 7
SAN SEBASTIAN, SPAIN

HENDRIKS AND VON STEENBERGEN B.V.
POMPUSLOON
POSTBUS 167
WEESP. HOLLAND

COMESA K.G.
0-1091 WIEN
SPITALGASSE 19
AUSTRIA

AMS/FRANCE (PAUL LOUIS)
14, 16, 18 RUE PAUL PAINLEVE
ZONE INDUSTRIELLE PMB
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PAGE 05 STATE 096631

95310 ST. OUEN L'AMMONE
FRANCE

MEDITRONIKA
C/SAN GERVOSIE DE CASSOLEA NO. 34
BARCELONA 22, SPAIN

DANBY AND HANCE LTD.
B-901 WATSON'S ESTATE
G.P.O. BOX 165
NORTH POINT, HONG KONG

MEDICAL SUPPLIES N Z LTD.
PRIVATE BAG, PONIRUN
NEW ZEALAND

JOHANN LEONARTZ GMBH
PAULINEANALICE 28-32
2000 HAMBURG 19
WEST GERMANY CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: LABELING, MEDICAL EQUIPMENT
Control Number: n/a
Copy: SINGLE
Draft Date: 14 apr 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE096631
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VB
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780162-0196
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780454/aaaabtmd.tel
Line Count: 195
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 139101b0-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2960013
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - REVISED PRODUCT LABELING (RECALL T-004-8)
TAGS: OGEN, ETRD, EIND, TBIO, AS, UK, IT, BE, SP, NL, AU, FDA
To: CANBERRA LONDON MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/139101b0-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014